UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

Cynthia R. Yanovich, et al.,	)	**CASE NO. 1:05 CV 2691**
	)	
Plaintiffs,	)	**JUDGE PATRICIA A. GAUGHAN**
	)	
vs.	)	
	)	
Sulzer Orthopedics, Inc., et al. ,	)	**Memorandum of Opinion and Order**
	)	
Defendants.	)	

Introduction

This matter is before the Court upon defendants' Motion for Summary Judgment (Doc. 29). This is a product liability action involving an artificial knee implant called Natural Knee II System (hereafter, NK II), which was manufactured by defendants and implanted in plaintiff Cynthia Yanovich's knees in 2003. For the following reasons, the motion is GRANTED.

Facts

Plaintiffs, Cynthia Yanovich (hereafter, Yanovich) and her husband, Michael Yanovich (collectively hereafter, plaintiffs), filed this Complaint in the Cuyahoga County Common Pleas Court against defendants, Dr. Stephen Helper and his Medical Group,

Hillcrest Hospital, Sulzer Orthopedics, Inc. (correctly identified by defendants as Zimmer Austin, Inc.) and Zimmer, Inc. After the dismissal of all defendants with the exception of Zimmer Austin, Inc. and Zimmer, Inc. (collectively hereafter, defendants), this matter was removed to this Court on the basis of diversity of citizenship.

In 2000, Yanovich was walking down a flight of stairs when she felt a "sudden sharp intense pain" in her left knee. Yanovich underwent arthroscopic surgery on her left knee in November 2000. After the surgery, Yanovich was informed that she had significant cartilage damage and required a total knee replacement. (pltf. depo. 58, 70, 72, 74-75)

In March 2002, Yanovich saw Dr. Stephen Helper for evaluation of her left knee. Dr. Helper sent Yanovich for physical therapy. The physical therapist noticed that Yanovich's right knee was not bending correctly and recommended that Yanovich have Dr. Helper examine that as well. Dr. Helper performed further arthroscopic surgery and determined that Yanovich needed total knee replacement surgery on both knees. (*Id.* 83-84, 89, 93-94)

On January 7, 2003, Yanovich underwent surgery on both knees. Dr. Helper performed total knee replacement surgery on both knees. (*Id.* 98-100) Yanovich was 45 years old. Dr. Helper implanted NK II components in both knees. Each NK II implanted included a femoral component, tibial component, tibial baseplate, tibial insert and patella button. The femoral component attaches to the end of the upper leg bone, the femur. The tibial baseplate attaches to the end of the lower leg bone, the tibia. The tibial insert is placed in the tray of the tibial baseplate and provides the surface on which the femoral component articulates. The patella button is the part that is used to replace the knee cap. The tibial insert and patella button are made of a type of plastic called ultra high molecular weight polyethylene. (expert

report of Charles R. Clark, M.D.)

Despite the use of significant pain medication, Yanovich continued to experience considerable pain following the surgery. (pltf. depo. 146-152) In March 2003, Dr. Helper did a surgical manipulation on both knees. In April 2004, due to ongoing pain, Yanovich sought another orthopedic opinion from Mary-Blair Matejczyk, M.D. (pltf. depo. 170-171) Dr. Matejczyk examined Yanovich and determined that she was "knock-kneed," meaning that her knees were in a valgus position. X-rays revealed a lateral subluxation in both knees. Dr. Matejczyk concluded that Yanovich's pain was intra-articular, that is coming from the knee joint. Dr. Matejczyk recommended that Yanovich have bilateral patella revisions with possible replacement of the right tibial insert. (Matejczyk depo. 9-16) On October 20, 2004, Dr. Matejczyk replaced both patellar components and the right tibial insert. (Clark report) This revision surgery revealed that both pegs of the petellas had fractured and the plastic petellas were off to the side, floating freely.

Plaintiffs thereafter filed this Complaint. Following dismissal of the above-mentioned defendants and the medical malpractice claim, only Count Two remains which alleges that the NK II is defective in design and manufacture. Plaintiffs assert that they proceed on a theory of strict liability. (Compl. ¶ 21). Plaintiffs thereafter disclosed the report of their expert, Erol Sancaktar, Ph.D., FASME.

This matter is now before the Court upon defendants' Motion for Summary Judgment.

Standard of Review

Summary Judgment is appropriate when no genuine issues of material fact exist and the moving party is entitled to judgment as a matter of law. *Celotex Corp. v. Catrett*, 477

U.S. 317, 322-23 (1986) (citing Fed. R. Civ. P. 56(c)); *see also LaPointe v. UAW, Local 600*, 8 F.3d 376, 378 (6th Cir. 1993). The burden of showing the absence of any such genuine issues of material facts rests with the moving party:

> [A] party seeking summary judgment always bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of "the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits," if any, which it believes demonstrates the absence of a genuine issue of material fact.

Celotex, 477 U.S. at 323 (citing Fed. R. Civ. P. 56(c)). A fact is "material only if its resolution will affect the outcome of the lawsuit." *Anderson v. Liberty Lobby*, 477 U.S. 242, 248 (1986).

Once the moving party has satisfied its burden of proof, the burden then shifts to the nonmoving party. Federal Rule of Civil Procedure 56(e) provides:

> When a motion for summary judgment is made and supported as provided in this rule, an adverse party may not rest upon the mere allegations or denials of [his] pleadings, but [his response], by affidavits or as otherwise provided in this rule, must set forth specific facts showing that there is genuine issue for trial. If he does not respond, summary judgment, if appropriate, shall be entered against him.

The court must afford all reasonable inferences and construe the evidence in the light most favorable to the nonmoving party. *Cox v. Kentucky Dep't. of Transp.*, 53 F.3d 146, 150 (6th Cir. 1995) (citation omitted); *see also United States v. Hodges X-Ray, Inc.*, 759 F.2d 557, 562 (6th Cir. 1985). However, the nonmoving party may not simply rely on its pleading, but must "produce evidence that results in a conflict of material fact to be solved by a jury." *Cox*, 53 F.3d at 150.

Summary judgment should be granted if a party who bears the burden of proof at trial

does not establish an essential element of his case. *Tolton v. American Biodyne, Inc.*, 48 F.3d 937, 941 (6th Cir. 1995) (citing *Celotex*, 477 U.S. at 322). Accordingly, "the mere existence of a scintilla of evidence in support of plaintiff's position will be insufficient; there must be evidence on which the jury could reasonably find for the plaintiff." *Copeland v. Machulis*, 57 F.3d 476, 479 (6th Cir. 1995) (quoting *Anderson*, 477 U.S. at 52 (1986)). Moreover, if the evidence is "merely colorable" and not "significantly probative," the court may decide the legal issue and grant summary judgment. *Anderson*, 477 U.S. at 249-50 (citation omitted).

Discussion

The Ohio Products Liability Act (OPLA), Ohio Revised Code §§ 2307.71-2307.80, governs strict liability claims in Ohio. Under the OPLA, a plaintiff can recover on a product liability claim only if he establishes, "by a preponderance of the evidence, that the product was defective in manufacture or construction, was defective in design or formulation, was defective due to inadequate warning or instruction, or because it did not conform to a representation made by its manufacturer." *Indiana Ins. Co. v. General Elec. Co.*, 326 F.Supp.2d 844, 855 (N.D. Ohio 2004) (citing Ohio Revised Code § 2307.73(A)(1)).

To recover on a products liability claim, it must be proven by a preponderance of the evidence that there was a defect in the product manufactured and sold by the defendant, such defect existed at the time the product left defendant's hands and the defect was the direct and proximate cause of the plaintiff's injuries or loss. *Id.*

(A) Medical Causation

Defendants argue that plaintiffs cannot maintain an action on any theory of defect because they cannot prove that any defect in the patellas medically caused Yanovich's alleged

injuries. For the following reasons, this Court agrees.

Under Ohio law, a plaintiff must present expert medical testimony to establish causation when he asserts a specific physical injury, the cause for which is not within common knowledge. *Conde v. Velsicol Chemical Corporation,* 24 F.3d 809 (6th Cir. 1994). To prove proximate causation for medical conditions or illnesses allegedly caused by a defective product, a plaintiff must show by a reasonable degree of medical certainty that the disease or injury was caused by the defective product. *Novak v. U.S.*, 865 F.2d 718 (6th Cir. 1989) ("The burden is upon the plaintiff in this case to establish proximate cause, and because it involves a medical condition or illness, the plaintiff must show by a reasonable degree of medical certainty that the disease was caused by the negligence of the government and/or by its defective product.") and *Kerpelis v. Pfizer, Inc.*, 2004 WL 1326771 (Ohio App. 7th Dist. June 7, 2004) (Summary judgment was warranted where the plaintiff did not introduce expert testimony to establish that a prescription drug was defective and that it was the proximate cause of plaintiff's injury because these are questions which lie outside the knowledge of lay witnesses.)

Defendants correctly point out that no orthopedic surgeon or other medical expert has opined that any defect in the patellas proximately caused Yanovich's injuries. Defendants expert, Dr. Charles Clark, on the other hand, an endowed professor of orthopedic surgery at the University of Iowa College of Medicine and a professor of biodmedical engineering at the University of Iowa College of Engineering, opined that the cause of the failure of the patellas was Yanovich's malalignment, in combination with Yanovich's biomechanics and other patient factors, and the fact that her physiology prevented the patellas from properly tracking

in her trochealer grooves. Dr. Clark explained:

> The undersurface of the patella is v-shaped and sits within a groove in the underlying femur. This groove is known as the trochlea or trochlear groove. The patella is free to slide up and down the trochlea, but the patella is not free to move laterally (from side to side). Therefore, the patella normally is contained by the walls of the trochlea. There are also fibrous restraints on both sides of the patella to keep its alignment central. With a normal functioning knee, the patella sits at the shallow section of the trochlea when the knee is extended. As the knee bends to about 30 degrees, the patella is pulled into the deeper part of the trochlea. After the knee passes 30 degrees of flexion, the patella runs centrally in the trochlea. However, if the patella is not properly aligned in the trochlea, the patella may partially come out of the groove. This is called subluxation.

Dr. Clark noted that Yanovich is a "heavy and short patient" with "short, heavy legs." Prior to her knee replacement surgery on January 7, 2003 her knees were in a varus position (bow-legged) and after the surgery, her knees were in a valgus position (knock-kneed). And,

> With a neutral mechanical axis, the stresses of the body's weight are evenly distributed over the contact surfaces of the knees. When the mechanical axis of the knee is in a valgus position, loads become relatively concentrated into the lateral compartment of the knee. The higher loading on the knee increases the stresses in that lateral compartment. In addition, with a valgus alignment greater than 5-6 degrees, the patella tends to sublux laterally.

Dr. Clark stated that Yanovich's complaints prior to the revision surgery were "typical of instability caused by valgus malalignment of the patella buttons." Because of this malalignment, "the patella buttons in both knees would sublux laterally. Thus, instead of gliding along the trochlear groove when Mrs. Yanovich bent her knees, her patella buttons would ride up on the edge of the trochlea." He stated such "subluxation imposes significant shear forces on the patella buttons, and those shear forces would be even more significant in a heavier patient with shorter, heavier legs." In pertinent part, Clark opined:

> It is my opinion that the mechanism of failure in Mrs. Yanovich's knees was multifactorial and primarily a biomechanical alignment issue. The malalignment of her patella buttons combined with her physiological factors resulted in significant

> shear forces being imposed on the patella buttons, which caused the patella buttons to fail. In addition, the flexion instability of the knee demonstrated by Dr. Stulberg added to the abnormal forces being imparted to the implants.

(Clark expert report at 7-9)

As defendants assert, plaintiffs do not offer any evidence of medical causation contradicting Dr. Clark's testimony, much less the expert evidence required in the Sixth Circuit. Plaintiff's engineering expert, Erol Sancaktar, Ph.D., a mechanical engineer, testified that he was not qualified to analyze the cause of Yanovich's medical condition:

> Q. You'd agree with me that you have no opinions about [Yanovich's] medical condition, correct?
>
> A. I cannot- - that's correct. Medically I cannot offer any ideas, yes.
>
> Q. Because you're not a doctor?
>
> A. That's correct.

(Sancaktar depo. 101). Further,

> Q. You don't hold any opinions about [Yanovich's] medical conditions?
>
> A. That's correct.
>
> Q. Your report doesn't contain any opinions about the nature of her alleged injuries?
>
> A. That's correct.

(*Id.* 102) Sancaktar also testified that he has no opinions about the alignment of Yanovich's patellas, or whether the patellas were subluxing; about whether Yanovich's patellas were malaligned; about the surgical technique used to implant the patellas; or about the packaging or warnings for Yanovich's patellas. He admitted that he is not qualified to diagnose malalignment. (*Id.* 96, 104-105)

Plaintiffs assert that expert testimony is unnecessary because it is within the layman's

common knowledge that Yanovich's kneecap buttons and fixation pegs were broken while in her knees, these devices were floating freely in her knees and this was discovered during the revision surgery wherein they were retrieved, extracted and replaced. Plaintiffs assert that it is within the layman's common knowledge that the fractured product caused Yanovich's injury. The cases relied upon by plaintiff are inapposite, however, because, unlike the case herein, those cases obviously do not require expert testimony.

In *Zalzal v. Scott*, 1 Ohio App.3d 151 (1st App. Dist. 1981), the court held that testimony by a shop's manager as to a customer's pulling him about by his necktie was sufficient to prove proximate cause of the manager's injuries and expert medical testimony was unnecessary. The court stated, "It is not absolutely necessary in all cases of physical injury to produce expert testimony to prove causal connection between tort and injury; because, when it is matter of common knowledge that certain acts will produce injury or pain, expert testimony is not required."

In *Bowling v. Indus. Comm.*, 145 Ohio St. 23 (1945), an expert medical witness was not necessary to prove that, when a liquid heated to 880 degrees Fahrenheit came into contact with the plaintiff's eye, it caused injury.

In *Dimora v. Cleveland Clinic Found*, 114 Ohio App.3d 711 (8th App. Dist. 1996), no expert testimony was required with respect to a claim that a student nurse who was attending an elderly patient had been negligent in moving away from the patient while the patient was walking from the bathroom given that the patient had serious balance difficulty, needed assistance in walking and had fallen backward on a previous occasion.

In *Wood v. Elzoheary*, 11 Ohio App.3d 27 (8th App. Dist. 1983), evidence was

presented that the plaintiff suffered neck and back injury in a motor vehicle accident and the court recognized that proof that the liability event caused the claimed injury need not include expert opinion testimony when the causal relationship is a matter of common knowledge.

The case herein goes beyond common knowledge. As evidenced by Dr. Clark's report, however, prescription devices like the NK II are complicated products whose performance is dependent on many factors and this lays beyond the knowledge of a lay person. Furthermore, other jurisdictions have similarly recognized the necessity of expert medical testimony in cases involving orthopedic medical devices.

In *Burton v. Danek Medical, Inc.*, 1999 WL 118020 (E.D.Pa. March 1, 1999), the court reiterated that in the absence of a causal relationship between the defendant's product and the plaintiff's injury, the defendant could not be held liable on any theory of liability. Because plaintiff failed to present admissible expert testimony that the medical device caused his injury, summary judgment was warranted.

In *Baker v. Danek Medical,* 35 F.Supp.2d 875 (N.D.Fla. 1998), summary judgment was warranted where there was no admissible medical causation evidence as to plaintiff's claim against the manufacturer of pedicle bone screws.

In *Love v. Danek Medical,* 1998 WL 1048241 (W.D.Ky. Nov. 25, 1998), summary judgment was warranted in the absence of medical causation evidence in a products liability action against the manufacturer of orthopedic surgical bone screws.

Because plaintiffs have no expert medical evidence showing that Yanovich was injured as a proximate result of a defect in the patellas, summary judgment is warranted on all of plaintiffs' claims.

(B) Manufacturing and Design Defect

Assuming plaintiffs' claims do not fail for want of medical causation evidence, defendants argue that the claims fail as a matter of law. For the following reasons, this Court agrees.

As stated above, to recover on a products liability claim, it must be proven by a preponderance of the evidence that there was a defect in the product manufactured and sold by the defendant, such defect existed at the time the product left defendant's hands and the defect was the direct and proximate cause of the plaintiff's injuries or loss. Plaintiff must provide expert testimony that the product is defective. *Kerpelis, supra.*

Defendants have filed a separate Motion in Limine seeking an order precluding plaintiffs from introducing testimony of Erol Sancaktar, Ph.D., plaintiffs' only expert witness, on the ground that his opinions do not meet the standards of admissibility under Federal Rule of Civil Procedure 702 or *Daubert.*

Even assuming that Sancaktar is permitted to testify, however, the Court agrees with defendants that plaintiffs still lack evidence of a defect in the patellas at the time of sale and, therefore, their claims still fail as a matter of law as discussed below.

(1) manufacturing defect

To establish a products liability claim for a manufacturing defect the plaintiff must establish, by a preponderance of the evidence that : (1) the product is defective in manufacture or construction; and (2) the defect was a proximate cause of the harm. O.R.C. § 2307.73. A product is defective in manufacture if, "when it left the control of its manufacturer, it deviated in a material way from the design specifications, formula, or

performance standards of the manufacturer, or from otherwise identical units manufactured to the same design specification, formula, or performance standards." O.R.C. § 2307.74(A). To succeed, a plaintiff must submit expert evidence that the product was defective in manufacture and the defect was the proximate cause of plaintiff's injury. *Loomis v. Medtronic, Inc.*, 2005 WL 1828763 (N.D.Ohio August 1, 2005).

Plaintiffs do not present evidence that the patellas deviated from defendants' specifications. Moreover, Dr. Sancaktar, plaintiffs' expert, agrees that the patellas met defendants' specifications in all regards. In particular, at deposition, Dr. Sancaktar testified that he had reviewed defendants' blueprints for patellar components. (Sancaktar depo. 130-131) Dr. Sancaktar testified,

> Q. Did you compare Mrs. Yanovich's patellar components to the blueprints?
>
> A. Yes.
>
> Q. Okay. Did you undertake any effort to determine whether Mrs. Yanovich's patellar components conformed to the blueprints?
>
> A. They did conform, yes.
>
> Q. Okay. It's your opinion then that Mrs. Yanovich's devices were consistent with [defendants'] blueprints for the devices?
>
> A. Yes.
>
> Q. Okay. You're not sitting here today offering the opinion that in some way her patellar components deviated from [defendants'] design?
>
> A. No.

(*Id.* 131)

Defendants offered their own engineering expert, Stephen Spiegelberg, Ph.D., who opines that "there was not material, design, or manufacturing defect in the patellar

components explanted from Mrs. Yanovich. The excellent clinical history of the three-peg all-polyethylene patellar component supports this assertion." (Stephen Spiegelberg report 17) Sancaktar's testimony does not contradict this testimony.

With the filing of their brief in opposition, plaintiffs submit a new affidavit of Erol Sancaktar, executed after the filing of defendants' Motion for Summary Judgment. Despite the fact that Sancaktar testified at deposition that Yanovich's patellas do not deviate from defendants' blueprints and were manufactured in conformance with defendants' specifications (set forth above), thus conceding that there is no claim based on a manufacturing defect, Sancaktar now avers,

> 5. Defendants' kneecaps and fixation pegs are defective in design and manufacture in that they left the defendant after having been submitted in the manufacturing process to E-beam irradiation and annealing that resulted in wide variations in strength and hardness. Disparate strength of the product at various points caused it to scar, pit and fracture prematurely while forces occasioned by the use of the knee were imposed on the product.
>
> 11. It is also my opinion that the explanted polyethylene knee buttons and fixation pegs were defective in manufacture or construction because they did not perform to the standards of the manufacturer and deviated from the design as shown by the greater hardness of the pristine sample kneecap button.
>
> 12. My opinion is that there is a relationship of cause and effect between the above-described design and manufacturing defects and weaknesses and the fracture failures of the knee buttons and fixation pegs that were removed from Mrs. Yanovich's knees.

(Sancaktar aff. ¶ 16)

To the extent that Sancaktar's new affidavit attests to a manufacturing defect, it conflicts with his prior sworn deposition testimony wherein he clearly stated that Yanovich's patellas conformed to defendants' blueprints and did not deviate from defendants' design. It

is well-established that a party cannot create an issue of fact to survive summary judgment by offering affidavit testimony that conflicts with prior sworn testimony. *Aerel, S.R.L. v. PCC Airfoils, L.L.C.*, 448 F.3d 899 (6th Cir. 2006) (citing *Cleveland v. Policy Mgmt. Sys. Corp.*, 526 U.S. 795 (1999) ("As the Supreme Court has observed, the lower federal courts have held with virtual unanimity that a party cannot create a genuine issue of fact sufficient to survive summary judgment simply by contradicting his or her own previous sworn statement (by, say, filing a later affidavit that flatly contradicts that party's earlier sworn deposition) without explaining the contradiction or attempting to resolve the disparity.") *See also Graham v. American Cyanamid Co.*, 2000 WL 1911431 (S.D.Ohio Dec. 21, 2000) (citing *Hughes v. Vanderbilt Univ.*, 215 F.3d 543, 549 (6th Cir.2000)) ("A party cannot create a factual issue by filing an affidavit which contradicts earlier deposition testimony after a motion for summary judgment has been made. If an affidavit is untimely and inconsistent with prior discovery responses, it is inadmissable and should not be considered.") Thus, Sancaktar's new opinion is inadequate to defeat summary judgment on the manufacturing defect claim.[1]

Plaintiffs assert that Sancaktar's affidavit opinion that the "kneecaps and fixation pegs are defective in design and manufacture in that they left the defendant after having been submitted in the manufacturing process to E-beam irradiation and annealing that resulted in

---

[1] This Court also agrees with defendants' additional assertion that Sancaktar's affidavit is insufficient to show an issue of fact as to a manufacturing defect because it is inadmissible under Evidence Rule 702 in that it lacks any scientific or evidentiary support. In particular, Sancaktar fails to identify any specification or design parameter with which the patellas failed to comply at the time of sale. Sancaktar testified at deposition that he inspected the patellas in 2006- well after the time they were sold. (Sancaktar depo. 77, 79)

wide variations in strength and hardness" is consistent with Sancaktar's deposition testimony[2] wherein he testified that defendants' e-beam processing fails to produce a uniform cross-linking or hardness. However, as pointed out by defendants, plaintiffs do not identify any of defendants' specifications requiring uniform cross-linking or hardness and, thus, this does not evidence a manufacturing defect. Moreover, defendants refer to Sancaktar's deposition wherein he testified that unused patellas have some variation in hardness. This would indicate that the patellas conform to defendants' specifications. Additionally, as recognized by Sancaktar in his affidavit, his opinions in this regard go to design rather than manufacture.

Because plaintiffs fail to show that when the patellas left defendants' control, they deviated in a material way from the design specifications, there is no evidence of a manufacturing defect in the patellas and summary judgment is warranted on the manufacturing defect claim. *White v. DePuy, Inc.*, 718 N.E.2d 450, 456 (Ohio App. 12th Dist. 1998) (Where there is no evidence concerning design specifications, formula, or performance standards of the manufacturer or of any failure by defendant to meet them, summary judgment is properly granted.) and *Loomis, supra.*

(2) design defect

"Ohio law authorizes recovery for injuries incurred as a result of a defectively designed product." *Miller v. Uniroyal Technology Corp.*, 35 Fed.Appx. 216, 222 (6th Cir. 2002) (citing O.R.C. § 2307.75(A)). To establish a design defect claim, a plaintiff must prove

---

[2] Plaintiffs fail to attach the portions of the deposition transcript relied upon. In fact, plaintiffs do not submit any testimony from witnesses except for the new affidavit of Sancaktar. Moreover, the factual section of plaintiffs' brief is practically devoid of any citation to evidence.

by a preponderance of the evidence that (1) the product manufactured and sold by the defendant had a design defect, (2) this defect existed at the time the product left the control of the manufacturer, and (3) the defect was the proximate cause of the injury for which recovery is sought. *Id.* (citing *State Farm Fire & Casualty Co. v. Chrysler Corp*., 37 Ohio St.3d 1 (1988)). This means the defect must be adequately identified. Where a plaintiff has no expert analysis or other evidence demonstrating that some aspect of the design was defective, the claim is dismissed." *McGrath v. General Motors Corp*., 26 Fed.Appx. 506, 511 (6th Cir. 2002) (citing *State Farm Fire & Casualty Co.*)

"A product is defective in design if (1) the foreseeable risks of the design exceed the benefits, or (2) the product is more dangerous than an ordinary consumer would expect when used in a reasonably foreseeable way." *Clay*, 215 F.3d at 669 (citing O.R.C. § 2307.75(A))

Pursuant to the risk-benefit test,

> the foreseeable risks of a design are determined by considering the following non-comprehensive list of factors: the nature and magnitude of the risks in light of the intended and reasonably foreseeable uses of the product; the likely awareness of the product's users of those risks; the likelihood that the design would cause harm in light of its intended and reasonably foreseeable uses; and the extent to which the product conformed to any applicable product standards that were in effect when it left its manufacturer.

Id. at 669. These risks, however, must be weighed against the following benefits associated with the products design: the utility of the product, including any performance or safety advantages associated with that design or formulation; the technical and economic feasibility, when the product left the control of its manufacturer, of using an alternative design or formulation; the nature and magnitude of any foreseeable risks associated with such an alternative design or formulation. *Id.* at 670 (citing O.R.C. § 2307.75(C)).

Under the consumer-expectation test, a product is defective in design if "[i]t is more dangerous than an ordinary consumer would expect when used in an intended or reasonably foreseeable manner." O.R.C. § 2307.75(A)(2). Pursuant to this test

> a product may be proven to be in a defective condition if (1) it is more dangerous than an ordinary consumer would expect when used in an intended or reasonably foreseeable manner, (2) the claimed defect was present when the product left the manufacturer, and (3) the claimed defect proximately caused the claimed injuries. *Hisrich v. Volvo Cars of North America*, 226 F.3d 445, 455 (6th Cir. 2000). 'Evidence of unsafe, unexpected product performance is sufficient to infer the existence of a product defect under the first prong of the consumer-expectation standard.' *Id.* (quoting *State Farm Fire & Cas. v. Chrysler Corp.*, 37 Ohio St.3d 1 (Ohio 1988)). 'The determination of whether a product is more dangerous than an ordinary person would expect is generally a question of fact which does not require expert testimony.' *Id*. (quoting *Fisher v. Ford Motor Co.*, 13 F.Supp.2d 631, 638 n. 10 (N.D.Ohio 1998)).

Tompkin v. Philip Morris USA, Inc., 362 F.3d 882, 901-902 (6th Cir. 2004).

(a) evidence of a defect

As discussed above, plaintiffs must present expert testimony that the patellas are defective in design. Pointing to Dr. Sancaktar's deposition testimony, defendants contend that plaintiffs' expert does not opine that the patellas are defective in design. This Court agrees. Sancaktar testified:

> Q. Okay. And you would agree with me, wouldn't you, that you've not reached the conclusion that the design of Mrs. Yanovich's patellar component is defective?
>
> A. Again, depends on the definition of defective. To me they are unsatisfactory. And I think if they- the damage that I saw in those patellar that were taken out**,** to me they will indicate defective products, yes.
>
> Q. When you say that they were unsatisfactory to you, they are unsatisfactory because they failed, correct?
>
> A. Not only because they failed but they also show to me unacceptable amount of variation in properties and also unacceptable levels of localized failure.

> Q. And unacceptable in terms of variation of properties and localized failure, that's unacceptable based on your standards, correct?
>
> A. Right.

(Sancaktar depo. 149-150) Further,

> Q. Okay. So in reaching the conclusions that you've made in your report is it fair to say that your conclusion is confined to this patellar component's design is unacceptable to you?
>
> A. Correct.

(*Id.* 151) And,

> Q. Okay. So when you talk about the design of a patellar component being unacceptable to you- -
>
> A. Correct.
>
> Q. That's based on looking solely at Mrs. Yanovich's devices, correct.
>
> A. Correct.

(*Id.* 153-154) Thus, Dr. Sancaktar's opinion is that the patellas are *unacceptable* because they failed. This is insufficient to constitute expert opinion that the design of the patellas is defective. Moreover, Dr. Sancaktar deposition testimony reveals that he cannot identify any literature reporting a failure of the NK II patella; he knows of no other NK II patellas that had failed; he does not know whether the success rate of NK II patellas was better or worse than other patellas available at the time; and he does not know the success rate for the NK II patellas. (*Id.* 84-86, 88-89, 123, 153-154)

Again, plaintiffs submit the newly executed affidavit of Dr. Sancaktar in support of their design defect claim. As to design defect, Sancaktar opines that "the Durasul components extracted from Mrs. Yanovich's knees are defective as follows":

> 1. In design and formulation because the ultimate manufactured product using Durasul has a wide variance in hardness from soft to hard. This variation in hardness is a result of the design calling for WIAM UHMPE. Selection of material is a design issue.
>
> 2. The product failed in situ because it was not hard enough to withstand the forces imposed on it while a component to the knee.
>
> 4. The defendants' product was defective in design because it was not strong enough at all locations to withstand the forces put to bear on it and therefore did not meet objective user expectations as to its durability and usefulness.
>
> 5. Defendants' kneecaps and fixation pegs are defective in design and manufacture in that they left the defendant after having been submitted in the manufacturing process to E-beam irradiation and annealing that resulted in wide variations in strength and hardness. Disparate strength of the product at various points caused it to scar, pit and fracture prematurely while forces occasioned by the use of the knee were imposed on the product.
>
> 6. The direct cause of the fractures of the polyethylene product in [Mrs. Yanovich's] knee implants was the weakness or lack of necessary strength of defendants' product in situ.
>
> 7. Also, the Durasul product is not fit for the use intended in that it is too weak to withstand the known load bearing requirements of the knee.
>
> 10. The precise event that triggered the failure of the Durasul implants is not nearly as important as the fact that at various locations the patella button is too weak to withstand requisite load bearing forces while at other locations it is dramatically stronger resulting in the fracture of the kind seen here.

(Sancaktar aff.) Finally, he states, "My opinion is that there is a relationship of cause and effect between the above-described design and manufacturing defects and weaknesses and the fracture failures of the knee buttons and fixation pegs that were removed from Mrs. Yanovich's knees." *(Id.*)

Plaintiffs appear to assert that this testimony is consistent with Dr. Sancaktar's deposition[3] wherein he testified that the weakness of the material caused the failure of the patellas:

> Q. But as you sit here today you don't know whether the cause of the cracking or pitting of Mrs. Yanovich's patellar devices was a medical factor, a surgical factor or some other factor, correct?
>
> A. Well, maybe it's the definition of cause. To me the cause of the failure was the weakness of the material.
>
> Q. Okay.
>
> A. And obviously something triggers that. But if the material is not weak, the trigger will not result in what we have observed. That's what I'm saying.

Defendants, however, point out that Dr. Sancaktar testified at deposition that he does not know whether the alleged variations in hardness (i.e., the design defect identified in his affidavit) caused the patellas to fracture:

> Q. Is it also accurate to say that you've not undertaken any effort to determine whether the hardness level of Mrs. Yanovich's device was such that it caused her patellar device to fracture?
>
> A. Correct. That's correct.
>
> Q. In other words, you know the hardness of her patellar components, correct?
>
> A. Correct.
>
> Q. But you don't know whether that hardness level caused the fracture of her devices?
>
> A. That's correct.

---

[3] Plaintiffs do not attach the portions of the transcript relied upon. In fact, plaintiffs' argument regarding design defect paraphrases Sancaktar's observations and opinions without citation to evidentiary support with the exception of one "See Sancaktar Affidavit."

> Q. And I want to ask you the same thing about crosslinking and crystallinity. You told me earlier you don't know the amount of crosslinking that had occurred in her device, correct?
>
> A. Correct.
>
> Q. And for that reason you don't know whether the lack of uniformity, if there is a lack of uniformity in Mrs. Yanovich's device caused her devices to fracture, correct?
>
> A. Correct.

(Sancaktar depo. 126-127)

Thus, Sancaktar admitted at deposition that he does not know whether his identified defect proximately caused Yanovich's patellas to fracture. While Sancaktar now opines in his new affidavit that "there is a relationship of cause and effect" between the hardness variation and the fracture of the patellas, this clearly contradicts his previously sworn testimony. On this basis, defendants are entitled to judgment as a matter of law.

(b) adequate warnings

Defendants additionally argue that plaintiffs' design defect claim fails because defendants' warnings were adequate.

"Generally, an adequate warning is a defense to design defect claims levied against prescription drugs. *See, e.g.*, Ohio Rev.Code § 2307.75(D) ("An ethical drug ... is not defective in design or formulation because some aspect of it is unavoidably unsafe, if the manufacturer of the ethical drug ... provides an adequate warning and instruction ... concerning that unavoidably unsafe aspect.") *In re Meridia Products Liability Litigation*, 328 F.Supp.2d 791, 815 (N. D. Ohio 2004).

It is not disputed that the patellas are prescription medical devices. Defendants assert there were proper warnings as to the inherent risks of subluxation, failure, or fracture of the

patellas. This Court agrees.

> Defendants' expert, Charles Clark, M.D., attests:
>
> 4. The package insert provided by defendants provides medically reasonable and adequate warnings regarding the risks associated with the Durasul Polyethylene Components of the [NK II] System. The [patellas] that the plaintiffs allege are defective are made from Durasul Polyethylene.
>
> 5. The package insert notifies physicians of the potential adverse effects that can occur with the patellar components, which include 'changing position of the prosthesis (bending, fracture and/or disassembly of components) with or without loosening or clinical symptoms.' ... The package insert also warns of the risks of 'subluxation, dislocation, decreased range of motion...'
>
> 6. Orthopedic surgeons are well aware of these risks, including the risks of subluxation, fracture and failure of the patellar component.
>
> 7. The warnings in the package insert adequately notify physicians of the risks associated with the patellar components.

(Clark aff.)

Defendants point out that Sancaktar has no opinions regarding any warnings provided by defendants and, in any event, such an opinion would be inadmissible given that he has admitted at deposition that he is not a physician and has no medical training. (Sancaktar depo. 30, 101, 104)

Plaintiffs argue that defendants' warnings were inadequate because they were not given to Yanovich and they did not warn that the NK II should not be used in patients that are short, stocky, have big upper legs, or are overweight. Nor, plaintiffs assert, does the warning state that the NK II cannot be used in knock kneed patients.

Under Ohio law, manufacturers of prescription products only have a duty to warn a patient's physician regarding risks. *Tracy v. Merrell Dow Pharmaceuticals, Inc.*, 58 Ohio St.3d 147, 149 (1991) ("Where a prescription drug has been prescribed for a patient by the

patient's physician, the manufacturer has been held to discharge its duty to warn if the manufacturer adequately warns the physician... This shift in the duty to warn has been called the learned intermediary doctrine.") As Clark's testimony is not contradicted that defendants properly warned Yanovich's surgeon, no warnings needed to be given to Yanovich, and defendants are entitled to judgment.

Significantly, moreover, plaintiffs provide no evidentiary support that the warnings were inadequate and do not designate expert medical testimony on the sufficiency of defendants' warnings. Thus, plaintiffs' unsupported contention that the NK II should not have been used on one with Yanovich's body type is unavailing.

(c) risk/benefit and consumer expectations test

Defendants assert that plaintiffs have no evidence (published articles, reports, or expert testimony) that the risk of the patellas' design outweigh the design's benefits.

Plaintiffs again rely on Sanckatar's newly executed affidavit[4] wherein he avers

> 3. Other stronger products were available for incorporation in the design at the time of manufacture including the previously used noncrosslinked polyethylene and other materials known to me and to the scientific community and were available at the time the defendant designed and manufactured the parts used in Mrs. Yanovich's knees.

(Sancaktar aff.)

Defendants point out, however, that Sancaktar's report did not identify a safer alternative design and Sancaktar previously testified at deposition that he could not identify a safer alternative design:

Q. You have no opinion about whether there were safer alternative designs available

---

[4] Plaintiff again provides no specific cites to evidence.

in 2003 for the patellar components?

A. Commercially, that's correct, I don't. But I have opinions about it, or concepts in my mind.

...

Q. ... You mentioned that you have concepts or theories in your head about safer designs for patellar components, correct?

A. Correct.

Q. Have you undertaken any efforts to determine whether or not any of those concepts that are in your head were actually in the marketplace in 2003?

A. I have not- - I'm not aware of any that are in the market, that's correct.

(Sancaktar depo. 130)

Thus, Sancaktar's new averment contradicts his earlier testimony and cannot create an issue of fact.

Sancaktar also testified that there is no patellar component "in existence today" that will not have the same rate of failure in clinical use. (Id. 122) And, when asked to identify "a single manufacturer who has made a patellar component that has a 100 percent success rate," Sancaktar responded, "They haven't made it but it can be made." (Id.) Further,

Q. I'm interested in knowing in actual clinical use is there any patellar component that you know of that has a more uniform crosslinking than [defendants'] patellar components?

A. I don't know of any in the market.

Q. And would the same thing be true with respect to the crystalline property that you've referred to? Is there any patellar component in clinical use that has a greater rate of crystallinity than [defendants'] patellar components?

A. I'm not aware of any.

> Q. Have you undertaken any effort to determine whether there are patellar components sold by other manufacturers that are more uniform in crosslinking or have greater crystallinity?
>
> A. I have not done that.
>
> Q. Have you undertaken any effort to determine whether there is a patellar component made by any manufacturer other that [defendants] with a better success rate than the Natural Knee patellar component?
>
> A. I did not investigate that.

(Id. 122-123) Further, when asked, "You don't hold any opinions about whether other designs were available in the marketplace in 2003 that were safer than [defendants'] designs for Mrs. Yanovich's patellar components?" Sancaktar responded, "That's correct." (Id. 129)

Thus, Sancaktar's earlier deposition testimony clearly contradicts his affidavit and plaintiffs cannot defeat summary judgment on this basis.

Defendants' experts, on the other hand, have attested to the utility of the NK II. Dr. Clark concluded that it has "an excellent clinical success rate" and Spiegelberg points to a 99.6% success rate. (Clark Report 9, Spiegelberg Report 10) Plaintiffs have presented no evidence to demonstrate that the patellas' risks outweigh their benefits. In fact, Sancaktar testified that he knew of no other NK II patellar component that has failed. (Sancaktar depo. 153-154) Plaintiffs argue, "It is obvious that the risks of using defendants' product outweigh any benefits of the product." (Doc. 35 at 12) But, plaintiffs are required to offer expert evidence to that effect and cannot rely on pure argument.

Because plaintiffs have no evidence of the existence of a safer alternative design that would have prevented Yanovich's injuries, defendants are entitled to judgment on the design defect claim. O.R.C. § 2307.75 (F) ("A product is not defective in design or formulation if, at

the time the product left the control of its manufacturer, a practical and technically feasible alternative design or formulation was not available that would have prevented the harm for which the claimant seeks to recover compensatory damages without substantially impairing the usefulness or intended purpose of the product.") *See also Jacobs v. E.I. DuPont de Nemours & Co.*, 67 F.3d 1219 (6th Cir. 1995).

Nor can plaintiffs succeed under the consumer expectations test. Plaintiffs do not dispute that no court in Ohio has applied the consumer expectations test to a prescription drug or medical device. Even if it did apply, plaintiffs present no evidence that the patellas' design failed to meet consumer expectations. On the other hand, defendants have presented evidence of the NK II's great success rate. (Spiegelberg Report 10, Clark Report 9) Plaintiffs argues that "the reasonable expectancy of the consumer is met" because a "customer objectively does not expect the artificial knee material to break within 22 months of implantation." (Doc. 35 at 9) This is insufficient to create an issue of fact to survive summary judgment.

For the foregoing reasons, plaintiffs claim based on a design defect fails.

(3) loss of constortium

Plaintiffs' loss of consortium claim fails because loss of consortium claims are derivative actions which depend on the existence of a primary cause of action. *Gearing v. Nationwide Ins. Co.*, 76 Ohio St.3d 34, 40 (1996) (holding parents' claim for loss of consortium is derivative

of their daughters' claims)

Conclusion

For all the above-stated reasons, defendants' Motion for Summary Judgment is

granted.[5]

IT IS SO ORDERED.

/s/ Patricia A. Gaughan
PATRICIA A. GAUGHAN
United States District Judge

Dated: 12/13/06

[5] As noted earlier, defendants have filed a Motion in Limine seeking to exclude plaintiffs' expert, Dr. Sancaktar. Because, as demonstrated herein, summary judgment is warranted even considering his testimony, the Court need to decide the Motion in Limine. Further, in its reply brief, defendants seek to strike Sancaktar's affidavit and unauthenticated documents offered by plaintiffs. This request is also unnecessary. Finally, defendants ask the Court to strike any new causes of action asserted in the brief in opposition. To the extent plaintiffs now attempt to assert claims under the Uniform Commercial Code, the claims are untimely. Similarly, plaintiffs arguments regarding common law liability fail for the same reasons discussed herein.